Clinical Evidence Summaries

Vascular Surgery

Meta-analysis: Superior efficacy of 3M™ Prevena™ Therapy for groin wounds in vascular surgery

Antoniou G, Onwuka C, Antoniou S et al. Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery. J Vasc Surg 2019; 70 (5):1700-1710.

Study Design

Meta-analysis and trial sequential analysis

To compare the efficacy of ciNPT with control in closed surgical wound incisions in vascular surgery

To compare the efficacy of Prevena Therapy with Standard Dressing in closed surgical wound incisions in vascular surgery

Methods

- Systematic Review of literature to identify RCTs comparing prophylactic ciNPT (Prevena Therapy) with Standard Dressing in closed groin incisions in vascular surgery.
- Fixed-effect model was used to calculate pooled odds ratio or risk difference and 95% confidence intervals.
- All studies identified compared Prevena Therapy to Standard Dressing.
- Primary outcome: Surgical Site Infection
- Secondary outcomes: revision surgery, in-hospital mortality, hospital length of stay, and readmission
- Identified 6 RCTs on a total of 733 groin surgical wounds: Prevena Therapy n=362 vs. Standard Dressing n=371 (all published between (2016-2018)
  - Gombert et al 2018
  - Engelhardt et al 2018
  - Pleger et al 2018
  - Kwon et al 2018
  - Lee et al 2017
  - Sabat et al 2016

Key Results

Surgical Site Infections

⬇56%

Reduction of risk of SSIs*
6 studies- Odd Ratio 0.36 (95% CI 0.24, 0.54) (p<0.001)*
Prevena Therapy 11.3% (41/362) vs
Standard Dressing 25.6% (95/371)

Revisions

⬇53%

Reduction of risk of Revision Surgery*
4 studies - Odd Ratio 0.44 (95% CI 0.22, 0.88) (p=0.02)*
Prevena Therapy 4.9% (13/268) vs
Standard Dressing 10.4% (28/270)

Length of Stay (LOS)

-2 days

Reduction of LOS*
2 studies
Weighted Mean Difference -2.14 days
(95% CI -3.78, -0.49) (p=0.01)*

Summary

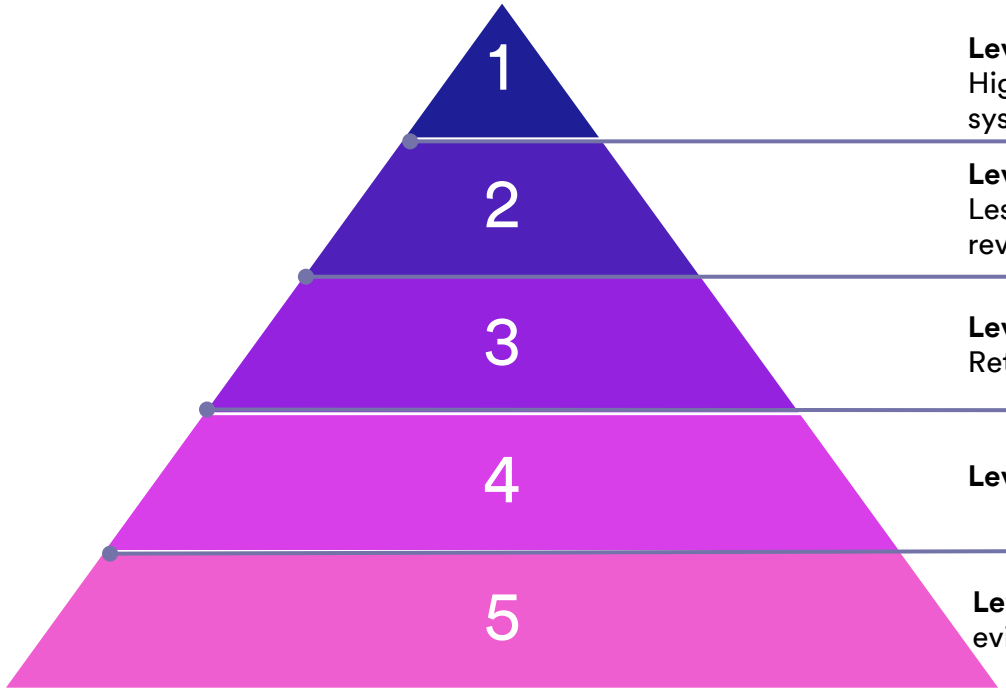
- Prophylactic use of negative pressure wound therapy (NPWT) helps improve over Standard Dressing through reduction in the risk of SSI in vascular surgical groin patients.
- Prevena Therapy patients have reduced risk for:
  - surgical site infection (p<0.0001)
  - revision surgeries (p=0.02)
- Shorter hospital stay for patients with Prevena Therapy (p=0.01)
- Differences in secondary outcomes in-hospital mortality and readmission were not statistically significant.
- "All studies included in our analysis were published recently (2016-2019) representing contemporary clinical practice in the Western world."
- "Evidence can be considered to be conclusive and that no more trials are required to investigate the primary outcome."

	3M™ Prevena™ Therapy		Standard Dressing			
	Events	Total	Events	Total	Estimate (95% CI)	P-value
Szilagyi I	22 (7.9%)	279	48 (16.6%)	289	OR 0.40 (0.24, 0.69)	**0.001***
Szilagyi II	12 (4.3%)	279	24 (8.3%)	289	OR 0.51 (0.25, 1.04)	0.06
Szilagyi III	3 (1.1%)	279	11 (3.8%)	289	RD -0.03 (-0.05, 0.00)	0.05

OR: Odd Ratio, RD: Risk Difference
†%- Risk-reduction is calculated based on Risk Ratio derived from related Odd Ratios and Prevalence Rate
*Statistically significant (p<0.05)

Negative Pressure Therapy for Incision Management

- For over 25 years, negative pressure vacuum-assisted closure (V.A.C.®) technology has been clinically shown to promote wound healing by reducing edema and promoting granulation tissue formation and perfusion through the removal of exudate and infectious materials.
- 3M extended the use of its negative pressure technology to closed surgical incisions with similarly positive clinical results, outlined in more than 200+ journal publications focused on closed incision negative pressure therapy (ciNPT)/3M™ Prevena™ Therapy.
- The Prevena Therapy clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale[1] and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care



Level 1:
High-quality, multicenter or single-center, randomized controlled trial with adequate power; or systematic review of these

Level 2:
Lesser-quality, randomized controlled trial; prospective cohort or comparative study; or systematic review of these studies.

Level 3:
Retrospective cohort or comparative study; case-control study; or systematic review of these studies

Level 4: Case series with pre/post test or only post test

Level 5: Expert opinion developed via consensus process; case report or clinical example; or evidence based on physiology, bench research, or “first principles”

Reference: 1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. Plast Reconstr Surg 2011;128(1):311-314

3M Prevena™ Therapy evidence table

Vascular

- The body of evidence for using Prevena Therapy has been growing steadily since its launch in 2010
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Control	Postoperative Clinical Endpoints* and institutional Health Economics
Groin Incision	1	Kwon (2018)	Femoral incisions following elective vascular surgery	Standard dressing	Surgical Site Complications (SSC); Surgical Site Infections (SSI) Readmission; Return to OR, Health Economics (HE)
		Gombert (2018)	Vascular surgery for Peripheral Artery Disease, Groin incisions	Standard dressing	SSI, Antimicrobial use, Bacteria in Swabs
		Pleger (2018)	Groin incision	Standard dressing	Wound Heling Complications, Local infections, 30 Day Revision Surgery
	3	Chang (2020)	Infrainguinal vascular surgeries involving upper thigh/groin incisions.	Standard dressing	Risk stratification, HE
		Frisbie (2020)	Proximal groin incisions, lower extremity bypass patients	Standard dressing	SSI, Deep SSI, HE
Lower Extremity or Groin Incision	3	Bernrashid (2020)	Lower Extremity or Infrainguinal incisions	Standard dressing	SSI, wound complications, Return to OR for wound complication
Amputation	3	Chang (2021)	Major Lower Extremity Amputation (BKA & AKA)	Standard dressing	Wound complications, SSIs (superficial and deep), necrosis, hematoma, readmission, revision surgery, and length of stay

* Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to Prevena Therapy. Individual results for each case may vary, depending on the patient, circumstances, and conditions.

RCT demonstrates 3M™ Prevena™ Therapy reduces major complications, reoperation, and readmission rates for high-risk groin incisions

Level of Evidence 1

Groin

Kwon J, Staley C, McCullough M et al. A Randomized Clinical Trial Evaluating Negative Pressure Therapy to Decrease Vascular Groin Incision Complications. Journal of Vascular Surgery. 2018; 68(6):1744-1752.

Study Design

Prospective, single-center, randomized controlled trial

Study Purpose

This prospective RCT evaluated negative pressure therapy (Prevena Therapy) to decrease wound complications and associated health care costs.

Methods

- The study included 119 femoral incisions closed primarily after elective vascular surgery procedures.
- High-risk inclusion criteria: BMI > 30, pannus, re-operative surgery, prosthetic graft, poor nutrition, immunosuppression, or HbA1c>8
- 1:1 Randomized to standard dressing (n=60) vs. Prevena Therapy (n=59)
- Outcomes evaluated at post-operative day 30: Wound Complications, SSI, Length of Stay (LOS), reoperation, readmission

Cost Assessment includes variable hospital costs (for both the index hospitalization and all readmission days within 30 days related to any wound complication). Hospital variable costs (not charges) for each admission were obtained by the authors from hospital administration. In the case of a contralateral complication, uncomplicated groin incision data were not included.

Key Results

Major Surgical Site Infections (SSIs)

↓53%

Reduction in Major SSIs*
10.1% (6/59) Prevena Therapy vs.
21.6% (12/60) Standard Dressing
(p=0.001)*

Wound Complication at 30 days)

↓55%

Reduction in Wound Complications*
11.9% (7/59) Prevena Therapy vs.
26.7% (16/60) Standard Dressing
(p=0.001)*

Readmissions

↓59%

Reduction in readmissions*
6.8% (4/59) Prevena Therapy vs.
16.7% (10/60) Standard Dressing
(p=0.04)*

Return to OR

↓2x

Reduction in return to the OR*
8.5% (5/59) Prevena Therapy vs.
18.3% (11/60) Standard Dressing
(p<0.05)*

	Prevena Therapy	Standard Dressing
Szilagyi I	1.7% (1/59)	3.3% (2/60)
Szilagyi II	3.4% (2/59)	5.0% (3/60)
Szilagyi III	5.1% (3/59)	11.7% (7/60)

Calculation(s) are derived based on the relative patient group incidence rate reported in this study; * Statistically significant (p<0.05)

Summary

- Study was evaluated and stopped at 80% enrollment target, as predetermined stop criteria for high-risk population were meet. Results demonstrated >50% reduction (p<0.001) in wound complication and reduced hospital costs with Prevena Therapy.
- Study suggests that negative pressure therapy for patients at high risk for groin wound complications significantly reduces major wound complication, reoperation and readmission rates and Prevena Therapy may lead to a reduction in hospital cost.
- The study authors calculated the potential cost saving per patient was $6045 (p=0.11) and report it is likely an underestimate as it does not include outpatient costs for infection treatment as well as readmission penalties.
- Prevena Therapy is recommended for all groin incisions considered at high risk for wound complications

Multi-center RCT demonstrates 3M™ Prevena™ Therapy reduces SSI in high-risk vascular surgery patients

Level of Evidence 1

Groin

Gombert A, Babilon M, Barbati M et al. Closed-incision negative-pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised multicentre trial (AIMS trial). Eur J Vasc Endovasc Surg. 2018; 56(3):442-448.

Study Design

Prospective, multi-center, randomized controlled trial

Study Purpose

This prospective RCT aimed to assess the potential benefit of Prevena Therapy application to reduce the surgical site infection risk after groin incision for vascular surgery.

Methods

- The study evaluated 188 patients who underwent vascular surgery for peripheral artery disease (PAD) with a longitudinal groin incision at two sites in Germany between July 2015 and May 2017.
- High-risk inclusion criteria: smoking; cardiac risk factors including hypertension, coronary heart disease, or history or myocardial infarction; and metabolic disorders including diabetes, dyslipidaemia, hyperhomocysteinaemia, or chronic renal failure.
- When a groin incision was performed on both sides, only one side was randomized and assess for the study.
- 30-day SSIs were assessed using the Szilagyi classification.

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Key Results

Szilagyi all (Szilagyi I, II, and III)

↓60%

Reduction in SSIs
13.2% (13/98) Prevena Therapy vs.
33.3% (30/90) Standard Dressing
(p=0.0015)*

Surgical Site Infection (Szilagyi I)

↓70%

Reduction in Szilagyi I SSIs*
8.1% (8/98) Prevena Therapy vs.
26.7 % (24/90) Standard Dressing
(p=0.0012)*

Antibiotic Treatment

↓58%

Reduction in Antibiotics
13.2% (13/98) Prevena Therapy vs.
31.1% (28/90) Standard Dressing
(p=0.004)*

Summary

- Study found Prevena Therapy was associated with a reduced incidence of SSIs and fewer Antibiotic Treatments for SSI when compared to Standard Dressing group.
- No device-related complications (skin laceration, allergic reaction, reduced mobility, or negative pressure related pain) or device failures were observed in this trial.
- High-risk patients could benefit from Prevena Therapy to help reduce the risk of total SSI.
- Subgroup analysis demonstrated for populations with increased SSI risk such as patient with PAD stage ≥3, BMI >25kg/m², and previous groin incisions a significantly reduced SSI rate with Prevena Therapy, indicating Prevena Therapy benefit for high-risk population.

SSI Rates per subgroups	Prevena Therapy	Standard Dressing	p-value
Szlagyi all	13.2% (13/98)	33.3% (30/90)	0.0015
BMI >25kg/m²	17% (10/59)	50% (25/50)	<0.001
PAD score ≥3	4% (2/46)	40.4% (17/42)	<0.001
Previous Groin Incision	10.8% (5/46)	33.3% (13/39)	0.016
Diabetes	14% (6/42)	36% (8/22)	0.06
CKD	16% (5/32)	27% (7/26)	0.34

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Gombert et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	98	90
Number of Surgical Site Infections (a)	13	30
Cost per SSI[1] (b)	$20,864	$20,864
Per Patient Infection Cost [c=(a*b)/n]	$2,768	$6,955
Per Patient Therapy Cost* (d)	$495	---
Total Cost Per Patient (c+d)	**$3,263**	**$6,955**
Potential Per Patient Savings Using Prevena Therapy	**$3,692**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18

*3M™ Prevena™ Peel and Place System Kit is an estimates; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy vs Standard Dressing. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Gombert A, Babilon M, Barbati M et al. Closed-incision negative-pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised multicentre trial (AIMS trial). Eur J Vasc Endovasc Surg. 2018; 56(3):442-448.

RCT Study demonstrates reduction in incision complications and revision procedures

Level of Evidence 1

Groin

Pleger SP, Nink N, Elzien M et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. Int Wound Journal 2018; 15(1):75-83.

Study Design

Single Center Randomized Controlled Trial

Study Purpose

The purpose of the study was to investigate the effectiveness of 3M™ Prevena™ Therapy compared to conventional therapy on vascular surgical groin incisions.

Methods

- Patients were randomized and treated with either Prevena Therapy or the Standard Dressing therapy, a conventional adhesive plaster.
- 100 patients with 129 groin incisions were analyzed: Prevena Therapy consisted of 43 patients/58 incisions; Standard Dressing consisted of 57 patients/71 incisions
- Inclusion criteria for high-risk patients: age > 50 years, diabetes mellitus, renal insufficiency, malnutrition, obesity and chronic obstructive pulmonary disease.
- Prevena Therapy was applied intraoperatively and removed on days 5–7 postoperatively.
- Wound evaluation based on the Szilagyi classification (adapted to include complications) took place postoperatively on days 5–7 and 30.

Key Results

Per Patient Evaluation

Local Surgical Site Infection

⬇87%

Reduction in Local SSI*
2.3% (1/43) Prevena Therapy vs.
17.5% (10/57) Standard Dressings
(p=0.022)*

Hematoma

⬇100%

Reduction in Hematomas*
0% (0/43) Prevena Therapy vs.
14% (8/57) Standard Dressings
(p=0.02)*

Per Incision Evaluation

Wound Healing Complications (WHC)

⬇80%

Reduction in Wound Healing Complications*
8.6% (5/58) Prevena Therapy vs.
42.3% (30/71) Standard Dressings
(p<0.0005)*

Wound Complications	Prevena Therapy	Standard Dressing	p-value
Total number	8.6% (5/58)	42.3% (30/71)	< 0.0005*
Szilagyi grade I	6.9% (4/58)	11.3% (8/71)	0.545
Szilagyi grade II	1.7% (1/58)	28.2% (20/71)	< 0.0005*
Szilagyi grade III	0	2.8% (2/71)	0.501

30 Day Revision Surgery

⬇88%

Reduction in Revision Surgery*
1.7% (1/58) Prevena Therapy vs.
14.1% (10/71) Standard Dressings
(p=0.022)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- With the use of Prevena Therapy after vascular surgery in high-risk patients, post-operative surgical site infections, wound complications, and revision surgeries were significantly reduced.
- Additionally, subgroup analysis revealed that Prevena Therapy had a significant effect in WHC reduction in patients with age >50 year, renal insufficiency, malnutrition and overweight.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Pleger et al Outcomes

Surgical Site Infection

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	43	57
Number of Infections (a)	1	10
Cost per Infection[1] (b)	$20,864	$20,864
Per Patient Infection Cost [c=(a*b)/n]	$485	$3,660
Per Patient Therapy Cost* (d) @$495x1.35	$668	---
Total Cost Per Patient (c+d)	**$1,153**	**$3,660**
Potential Per Patient Savings Using Prevena Therapy	**$2,507**	

Surgical Site Complication

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Incisions (n)	58	71
Number of Complications (a)	5	30
Cost per Complication[2] (b)	$18,325	$18,325
Per Incision Complication Cost [c=(a*b)/n]	$1,580	$7,743
Per Incision Therapy Cost* (d)	$495	---
Total Cost Per Incision (c+d)	**$2,075**	**$7,743**
Potential Per Incision Savings Using Prevena Therapy	**$5,668**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18

2. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

*3M™ Prevena™ Peel and Place System Kit is an estimate; individual prices may vary. Per patient Prevena Therapy Cost accounts for 1.35 Incisions/patient.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or Standard Dressing. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Key Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Pleger SP, Nink N, Elzien M et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomized, single-institution study. IntWound J 2018; 15(1):75-83.

Risk-stratification to identify high-risk patients leads to potential cost savings

Level of Evidence 3

Groin

Chang B, Sun Z, Peiris P et al. Deep learning-based risk model for best management of closed groin incisions after vascular surgery. Journal of Surgical Research 2020;254:408-406

Study Design

Single center retrospective cohort study (Level III)

Study Purpose

Primary objectives:

- Apply a prediction model to a cohort of vascular surgery patients to assess the appropriate use of 3M™ Prevena™ Therapy for the management of incisions after vascular surgery
- Assess impact of adoption of this prediction model on financial outcomes

Methods

- A deep learning-based, risk-based prediction model was retrospectively applied to a data set of 370 patients undergoing vascular surgery at Duke University.
- Prevena Therapy or standard dressings were applied over closed incisions at the surgeon's discretion.
- Predictive risk scores were generated for each patient and used to categorize patients as "high" and "low" predicted risk for SSI.
- Patients were further divided into four groups for analysis: (1) low-risk patients who received Standard Dressing, (2) low-risk patients who received Prevena Therapy, (3) high-risk patient who received Standard Dressing, and (4) high-risk patients who received Prevena Therapy
- SSI event rates were calculated for each group

Key Results

Surgical Site Infections

↓67%

Reduction in Surgical Site Infections
6.8% (10/148) High-risk Prevena Therapy vs. 20.9% (28/134) High-risk Standard Dressing (p<0.001)*

Potential Cost Reduction with risk-stratification and Prevena Therapy

↓26%

Average Per-Patient Cost
Prevena Therapy on high risk: $**1143 (medium range estimate)**
No risk stratification **$ 1,544 (actual)**
Mean per Patient Cost Savings**: $401(medium range estimate)**

Additional Results

Retrospective Risk Stratification	Prevena Therapy	Standard Dressing	p-value
Actual SSI Rate in High-Risk Population	6.8% (10/148)	20.9% (28/134)	<0.001*
Actual SSI Rate in Low-Risk Population	9.7% (3/31)	8.8% (5/57)	0.99

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
*Statistically significant (p<0.05)
Cost estimates were calculated by the study authors using assumptions described in the article and presented as low, medium and high. The medium cost saving is presented.

Summary

- Retrospective application of the predictive model to the patient population suggested that only 55.4% of patients were appropriately matched with their intervention (158 high risk patients receiving Prevena Therapy, 57 low risk patients receiving SOC).
- If 100% of patients were matched appropriately by their risk profile to an intervention (perfect utilization), the predicted SSI events in the entire cohort would be 7.3% *(versus 12.4% in actual study population).*
- Applying the risk-based model with perfect utilization of Prevena Therapy projected a medium cost reduction of 26% ($401) per patient considering already for the Prevena Therapy cost. This corresponds to a relative SSI rate reduction of 41.3%.
- Using a risk prediction model to aid decision making in the care of closed incisions after vascular surgery can help optimize the utilization of Prevena Therapy, outcomes, and associated costs.

Potential reduction in incisional wound complications when using 3M™ Prevena™ Therapy

Level of Evidence 3

Groin

Frisbie JJ, Bordoli S J, Simmons J M, Frisbie JJ, Zuiderveen SK. Utilizing closed incisional negative pressure therapy reduces peripheral bypass infection rates without increasing costs. Cureus. 2020 Jul 16;12(7):e9217.

Study Design

Retrospective before/after comparative cohort study (Level III)

Study Purpose

The study investigated the effect of Prevena Therapy on the incidence of surgical site infections (SSI) and cost effectiveness of its use for vascular bypass patients

Methods

- Retrospective review of outcomes before and after institutional implementation of Prevena Therapy.
- The Standard Dressing group, (standard wound dressings) consisted of 102 patients who underwent lower extremity bypass surgery between September 2017 and April 2018.
- The Prevena Therapy group included of 113 patients from September 2018 and April 2019.
- Study endpoints determined at day 30: total SSI, deep SSI and superficial SSI and on year follow up for graft infections.
- Cost analysis was separately performed utilizing hospital metrics.

Key Results

Surgical Site Infection

↓70%

Reduction in SSIs*
3.5% (4/113) Prevena Therapy vs.
11.8% (12/102) Standard Dressing
(p=0.0218)*

Deep Surgical Site Infection†

↓87%

Reduction in DSSIs*†
0.9% (1/113) Prevena Therapy vs.
6.9% (7/102) Standard Dressing
(p=0.0169)*

Cost Savings

↓44%

Reduction in Per Patient Cost for SSI
$912 Prevena Therapy vs.
$1,618 Standard Dressing
Per Patient Cost Savings: **$706**

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)
† **NOTE:** The use of Prevena Therapy for reduction in the incidence of deep SSI has not been reviewed by the U.S. FDA

Summary

- Prevena Therapy resulted in a decrease in surgical site infections.
- Reduced SSI rate led to a minimum of $62,000 in infection related cost savings between the two groups in this study, even when accounting for the total cost of Prevena Therapy.
- As a result of this study, the institution implemented routine use of Prevena Therapy for all lower extremity vascular bypass patients.

3M™ Prevena™ Therapy helped reduce Surgical Site Infections in an SSI care bundle

Level of Evidence 3

Lower Extremity

Benrashid E, Youngwirth LM, Guest K, Cox MW, Shortell CK, Dillavou ED. Negative pressure wound therapy reduces surgical site infections. J Vasc Surg. 2020 Mar;71(3):896-904

Study Design

Single center retrospective study (Level III)

Study Purpose

Primary objective of the study was to determine whether the use of Prevena Therapy decreased perioperative SSIs in vascular surgery patients

Methods

- Retrospective analysis of all patients with lower extremity or infrainguinal incisions between January 2016 and December 2017
- A multidisciplinary team created a vascular surgery specific SSI reduction bundle which included preoperative optimization of anemia and glucose management, standardized preparation with chlorhexidine gluconate-based solutions, standardized preoperative hair clipping, and appropriate antibiotic administration. Intraoperatively, OR traffic was limited, normothermia and euglycemia was maintained, and a dedicated wound closure tray was used.
- All patients were treated with the same perioperative care bundle to reduce SSI.
- Prevena Therapy, not part of the bundle, was applied at the discretion of the surgeon in 225 patients. 279 patients received standard dressings.
- The 90-day outcomes were SSI, any wound complication, return to operating room, death, and readmission.

Key Results

Surgical Site Infections (SSIs)

↓48%

Reduction in SSIs*
9.8% (22/225) Prevena Therapy vs.
19.0% (53/279) Standard Dressing
(p<0.01)*

Surgical Site Complications (SSCs)

↓34%

Reduction in SSCs*
20.0% (45/225) Prevena Therapy vs.
30.5% (85/279) Standard Dressing
(p<0.01)*

Mortality

↓48%

Reduction in 90-day mortality*
5.8% (13/225) Prevena Therapy vs.
11.2% (31/279) Standard Dressing
(p=0.04)*

Return to operating room related to SSC

↓46%

Reduction in return to the OR*
26.2% (16/225) Prevena Therapy vs.
48.3% (37/279) Standard Dressing
(p<0.01)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Summary

- In a population undergoing vascular surgery with an SSI care bundle implemented, patients that received Prevena Therapy had decreased SSIs, SSCs, mortality, and reoperations for wound related complications (seroma, infection, nonhealing incision, dehiscence).
- Readmissions, length of stay, major amputations, and reoperations (for any reason) were not significantly different between groups.
- Improved outcomes were observed in the Prevena Therapy group despite having significantly more women, more active smokers, and increased operative times (all of which are factors associated with increased infections and complications).
- A multiple logistic regression analysis , demonstrated a decreased risk of SSI for Prevena Therapy patients (OR 0.32; 95% CI 0.17-0.63; p<0.01).
- Using Prevena Therapy devices as part of institutional perioperative SSI reduction care bundles may help mitigate SSI risk and wound complications in patients undergoing infrainguinal vascular surgical procedures.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Benrashid et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	225	279
Number of Surgical Site Infections (a)	22	53
Cost per SSI[1] (b)	$20,864	$20,864
Per Patient Infection Cost [c=(a*b)/n]	$2,040	$3,963
Per Patient Therapy Cost* (d)	$830	---
Total Cost Per Patient (c+d)	**$2,870**	**$3,963**
Potential Per Patient Savings Using Prevena Therapy	**$1,093**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18

*3M™ Prevena™ Plus Customizable Dressing is an estimate; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy versus Standard Dressings. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Benrashid E, Youngwirth LM, Guest K, Cox MW, Shortell CK, Dillavou ED. Negative pressure wound therapy reduces surgical site infections. J Vasc Surg. 2020 Mar;71(3):896-904

Decreased rate of wound complication occurrence observed in patients with vascular disease undergoing major lower extremity amputation

Level of Evidence 3

Amputations

Chang H, Maldonado TS, Rockman CB, Cayne NS, Berland TL, Barfield ME, Jacobowitz GR, Sadek M. Closed incision negative pressure wound therapy may decrease wound complications in major lower extremity amputations. Journal of Vascular Surgery. 2021 Mar;73(3):1041-1047.

Study Design

Retrospective, comparative study (Level III)

Study Purpose

This study evaluated closed incision negative pressure therapy (ciNPT; 3M™ Prevena™ Therapy) vs. standard dressings in decreasing the complication risk in patients with peripheral vascular disease undergoing major lower extremity amputations (LEAs)

Methods

- The study included 54 patient limbs with history of peripheral arterial disease that underwent below-knee or above-knee amputations
- Retrospective review of prospectively maintained database from Jan 2018 to Dec 2019
- 23 amputations in the NPWT group and 31 amputations in the standard dressing group (Standard Dressing)
- Patients in the NPWT arm of the study presented a higher incidence of comorbidities (tobacco use, previous amputation, COPD, etc.) vs Standard Dressing group
- Amputation incisions assessed and wound complications recorded 30 days postoperatively.
- Outcomes included: Surgical Site Infections, Wound Complications, Necrosis, Hematoma, Readmission, Revision Surgery, and Hospital Length of Stay (LOS)

Key Results

Wound Complications

⬇67%

Reduction in SSCs*
13 % (3/23) Prevena Therapy vs.
39 % (12/31) Standard Dressing
(p=0.037)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study
* Statistically significant (p<0.05)

Additional Outcomes

Outcome	Prevena Therapy	Standard dressing	p-value
Overall Wound Complications	13% (3/23)	39% (12/31)	**0.037***
Deep SSI†	4% (1/23)	13% (4/31)	0.283
Superficial SSI	4% (1/23)	10% (3/31)	0.460
Necrosis†	4% (1/23)	13% (4/31)	0.283
Hematoma†	0% (0/23)	3% (1/31)	0.385

† **NOTE:** The use of Prevena Therapy for the reduction in the incidence of deep SSI, skin necrosis, and hematoma has not been reviewed by the U.S. FDA

Summary

- Perioperative wound complications were significantly reduced within the Prevena Therapy group although there were increased comorbidities and risk factors.
- The reduction of perioperative wound complications and superficial SSI was statistically significant while there was no difference in other outcomes measured.
- Study suggest that Prevena Therapy may reduce the incidence of wound complications in vascular patients undergoing major lower extremity amputations, including high risk patients.
- Prevena Therapy may be considered for use in major lower extremity amputations.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Chang et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	23	31
Number of Surgical Site Complications (a)	3	12
Cost per SSC[1] (b)	$9,526	$9,526
Per Patient Complication Cost [c=(a*b)/n]	$1,243	$3,687
Per Patient Therapy Cost* (d)	$830	---
Total Cost Per Patient (c+d)	**$2,073**	**$3,687**
Potential Per Patient Savings Using Prevena Therapy	**$1,615**	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

*3M™ Prevena™ Plus Customizable Dressing is an estimate; individual prices may vary

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or Standard Dressings. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Chang H, Maldonado TS, Rockman CB, Cayne NS, Berland TL, Barfield ME, Jacobowitz GR, Sadek M. Closed incision negative pressure wound therapy may decrease wound complications in major lower extremity amputations. Journal of Vascular Surgery. 2021 Mar;73(3):1041-1047.

3M™ Prevena™ Therapy for the high-risk Vascular Surgery patient

Inclusion criteria for patients at high-risk for complications:

Groin Incisions

Patients are high-risk if they have ≥ 1 of the following risk factors:

- Re-operative surgery
- Prosthetic vascular graft
- Age > 50 years
- BMI > 30 kg/m^2
- Significant pannus
- Malnutrition
- Smoker
- Immunosuppression
- Cardiac risk factors
    - hypertension
    - coronary heart disease
    - history or myocardial infarction
- Chronic obstructive pulmonary disease (COPD)
- Uncontrolled diabetes (hemoglobin A1c >8%)
- Chronic kidney disease
- Dyslipidaemia
- Hypercholesterolaemia
- Hyperhomocysteinaemia

References:

1. *Kwon J, Staley C, McCullough M et al. A randomized clinical trial evaluating negative pressure therapy to decrease vascular groin incision complications. Journal of Vascular Surgery. 2018; 68(6):1744-1752.*
2. *Gombert A, Babilon M, Barbati M et al. Closed-incision negative-pressure therapy reduces surgical site infections in vascular surgery: a prospective randomised multicentre trial (AIMS trial). Eur J Vasc Endovasc Surg. 2018; 56(3):442-448.*
3. *Pleger SP, Nink N, Elzien M et al. Reduction of groin wound complications in vascular surgery patients using closed incision negative pressure therapy (ciNPT): a prospective, randomised, single-institution study. IntWound J 2018; 15(1):75-83.*